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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,162	01/16/2002	John H. Crowe	800189-0012 (6829-60508)	3071

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EXAMINER

CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,162

Applicant(s)

CROWE ET AL.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-21, 24, 26-34, 43, 44, 46-49 and 62-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-21, 24, 26-34, 43, 44, 46-49 and 62-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' amendment filed 10-27-03 has been entered. Claims 1-15, 22, 23, 25, 35-42, 45 and 50-61 have been canceled. Claims 16, 17, 20, 21, 24, 43, 46 and 48 have been amended. Claims 62-96 have been added. Claims 16-21, 24, 26-34, 43, 44, 46-49 and 62-96 are pending and under consideration.

#### ***Information Disclosure Statement***

1. The information disclosure statement filed 10-27-03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. No legible copy of the cited reference can be found in the parent application 09/828,627.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 16-21, 24, 26-34, 43, 44, 46-49 and 62-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants' amendment filed 10-27-03 necessitates this new ground of rejection.

The phrase "temperature range selected from a group of temperature ranges comprising..." in claims 16, 43 and 62 is vague and renders the claims indefinite. The term

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“comprising” is an open language term and it means there is something else other than the listed low, intermediate and high phase transition temperature ranges. It is unclear what other temperature range is intended to be in the group of temperature ranges. Thus, claims 16, 43 and 62 are indefinite. Claims 17-21, 24, 26-34 and 76-85 depend on claim 16. Claims 44, 46-49 and 87-96 depend on claim 43. Claims 63-75 and 86 depend on claim 62. Those dependent claims fails to clarify the indefiniteness.

The phrase “temperature range selected from the group of temperature ranges” in claim 17 is vague and renders the claim indefinite. It is unclear what “group of temperature ranges” is intended.

4. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how to increase the loading efficiency of the oligosaccharide into the erythrocytic cell.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 78 and 89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and/or use the invention. Applicants' amendment filed 10-27-03 necessitates this new ground of rejection.

Claims 78 and 89 are newly added claims. Claims 78 and 89 specify the alcohol comprises from 25 to 27 carbon atoms.

The phrase "alcohol comprises from 25 to 27 carbon atoms" is considered new matter. The specification fails to provide support for the alcohol having from 25 to 27 carbon atoms in a membrane. The amendment filed 10-27-03 fails to point out where in the specification provides support for an alcohol comprising from 25 to 27 carbon atoms in a membrane. Thus, claims 78 and 89 are rejected under 35 U.S.C. 112 first paragraph for introducing new matter into the claims.

7. Claims 16-21, 24, 26-34, 43, 44, 46-49 remain rejected and claims 76-85 and 87-96 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for loading an oligosaccharide into erythrocytic cells by removing at least a portion of cholesterol from said erythrocytic cells and disposing the erythrocytic cells in an oligosaccharide solution for loading the oligosaccharide into said erythrocytic cells *in vitro*, does not reasonably provide enablement for a process for loading an oligosaccharide into erythrocytic cells by removing at least a portion of any alcohol from said erythrocytic cells and disposing the erythrocytic cells in an oligosaccharide solution for loading the oligosaccharide into said erythrocytic cells *in vitro* or *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims and is repeated for the reasons set forth in the

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preceding Official action mailed 6-27-03 (Paper No. 5). Applicant's arguments filed 10-27-03 have been fully considered but they are not persuasive.

Claims 76-85 and claims 87-96 are newly added claims. Claims 76-85 depend on claim 16. Claims 87-96 depend on claim 43.

Applicants argue that there is no need to test every species covered in the claims for the enablement of said claims and applicants are entitled to broadly claim "alcohol" without having to conduct experiment for every alcohol species (amendment, p. 16-18). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 6-27-03 (Paper No. 5). Although there is no need to test every species covered in the claims for the enablement of said claims, the specification must provide sufficient enabling disclosure for the claimed invention. As discussed in the preceding Official action, alcohol is a very broad term and includes methanol, ethanol, propanol, glycerol, ethylene glycol, and fatty alcohol etc. The specification only discloses removing a portion of cholesterol from the erythrocytic cells before loading said cells with oligosaccharide. The specification fails to provide adequate guidance and evidence for removing any type of alcohol other than cholesterol from erythrocytic cells before loading oligosaccharide such that improved loading efficiency of oligosaccharide into erythrocytic cells could be obtained as compared to control erythrocytic cells that no alcohol has been removed from said control erythrocytic cells before loading oligosaccharide *in vitro* or *in vivo*. Further, the specification indicates that cholesterol-depleted erythrocytes have three phase transition temperature ranges, however, the control erythrocytes only have two phase transition temperature ranges (see specification, p. 58, 59, Table III). The specification fails to provide adequate guidance and evidence whether removing any alcohol other than cholesterol from

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erythrocytes can result in three phase transition temperature ranges as the cholesterol-depleted erythrocytes. Thus, the specification fails to provide sufficient enabling disclosure for the claimed invention. Therefore, claims 16-21, 24, 26-34, 43, 44, 46-49 remain rejected and claims 76-85 and 87-96 are rejected under 35 U.S.C. 112 first paragraph.

### ***Conclusion***

No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. Due

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to the move of USPTO to new site in Alexandria, Virginia, examiner's telephone number will be changed to (571) 272-0726 **after January 12, 2004**. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

A handwritten signature in cursive script, appearing to read 'S Chen', located to the right of the typed name.